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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/008,722 | 12/06/2001 | Kei Roger Aoki | 16952CON1DIV5CIP1 | 5741 |

7590
Stephen Donovan
Allergan, Inc.
2525 Dupont Drive, T2-7H
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10/02/2003

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| EXAMINER |
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GUPTA, ANISH

| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,722

Applicant(s)

AOKI ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of Claim

1. In the Patent Application, 08/627,118, an interference was declared between said Application and US Patent No. 5,766,605 (Sanders et al.). The Board of Appeals and Patent Interferences concluded, on February 26, 2002, that Sanders was not entitled to claims 1 and 13-18 in the U.S. patent, the count corresponding to the treatment of sweat. The Board further concluded that the subject matter of claims 60-71, corresponding to Count 3 (i.e. treatment of rhinorrhea subject matter), was not entitled to Applicants of Application 08/627,118. This Application is a continuation-in-part of 09/487,477 which was a divisional of Application 08/627,118. Rejections based Board's ruling, for claims 21-38, follow below.

Terminal Disclaimer

In a letter dated, 3-4-02, Applicants stated that they submitted two terminal disclaimers over 09/490,754 and 08/627,118. However, the terminal disclaimers were never received in the application. Further, it is believed that terminal disclaimers are unnecessary at this time. The claimed subject matter in both applications, 09/490,754 and 08/627,118, was amended to limit the scope to sweat. The Board had determined that Applicants were entitled to claims drawn to sweat in 08/627,118. Since the current claims are drawn to mucus secretion and Applications claimed subject matter is drawn to sweat an obviousness type double patenting rejection is not applicable. As such, a terminal disclaimer is unnecessary at this time.

Estoppel

§1.658 Final Decision:

(c) A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under §1.633 (a) through (d) and (f) through (j) or §1.634, and (3) could have been properly raised and decided in an additional

interference with a motion under §1.633(e). A losing party who could have properly moved, but failed to move, under §1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.

2. Claims 1-16 are rejected on the grounds of estoppel under rule 37 CFR 1.658(c).

Applicants have copied the claims of Sanders et al. and attempting to provoke interference under 1.607(c).

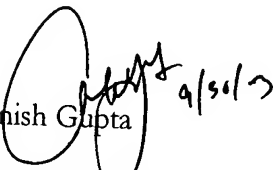
The claims are drawn to a method of treating mucus secretion of a patient using botulinum toxin and wherein the mucus secretion is not a symptom of rhinorrhea.

The MPEP states "Claims which cannot be rejected as unpatentable over the lost counts may still be subject to rejection on the ground of estoppel", specifically referring to 1.658(c). See MPEP 2363.03. The claimed subject matter in the instant Application could have been brought forth before the Board of Appeals in an interference proceeding. Rule 1.633(c) recites that a motion can be filed to redefine the interfering subject matter. Thus, Applicants could have moved under 1.633(c) to bring this Application in the interference proceedings to declare interference between this Application and the U.S. Patent 5,766,605. Note that the claimed subject matter of claims of the instant Application is similar to Count 3 of the subject matter in the interference between 08/627,118 and U.S. Patent 5,766,605 and could have been the basis of an additional counts wherein the mucus secretion was not a symptom of rhinorrhea. However, Applicants did not file a proper motion under 1.633 and is therefore "estopped from taking subsequent action in the USPTO which is inconsistent with the party's failure to properly move" in this Application. See MPEP 2363.03. Note, that this application was filed on December 6, 2001 and the interference between 08/627,118 and Sanders was declared March 29, 2001 and a decision was made on February 26, 2002. Thus,

upon filing of this Application, Applicants could have timely moved under 1.633(c). Applicants are requested to review Example 6 in this section since it most closely resembles this situation.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner